HB 2268 - INCREASE IN PUBLIC HEALTH LABORATORY FEES
(HEALTH DIVISION, DHS)

BACKGROUND:

- The Health Division's Public Health Laboratory (PHL) screens all Oregon newborns for six disorders ~hypothyroidism, PKU, sickle cell disease, etc.). These are genetic defects in body chemistry which, if untreated, can cause profound mental retardatiorn and other serious disabilities, or death. The PHL operates the Northwest Regional Newborn Screening Program, which provides this service to five states (OR, ID, AK, NV, HI) - a total of 130,000 infants per year.

- New technology (tandem mass spectrometry or MS/MS) allows expansion of testing to include another 20+ disorders, some of which may be fatal if untreated. Taken together, these additional disorders have an incidence of at least one in 5,500 live births.

- Oregon infants should also be screened for congenital adrenal hyperplasia (CAH), a potentially fatal disorder which occurs in one of every 12,000 live births. The PHL already provides this service to Hawaii and Alaska

- Other advances in medicine, genetics, and laboratory practice will soon make it possible to screen for and treat other disorders such as cystic fibrosis.

- The PHL charges fees for a small number of communicable disease rests for private practitioners, such as HIV and hepatitis C serologies. These are not funded by GF but are important for disease control.

NEED FOR STATUTORY CHANCE:

Newborn Screening

- The newborn screening program is funded entirely by fees, which are capped in statute at $16 per specimen. Currently, the fee has reached $16, of which $11 goes for newborn screening and $5 subsidizes communicable disease testing unrelated to newborn screening (hepatitis, STDs, tuberculosis, etc.) for local health departments. The fee cap was last increased in 1993.

- To adopt MS/MS will require a fee increase of $6 per specimen, and to adopt CAH screening will require an additional $2 per specimen.

- The PHL's assays for galactosemia and biotinidase deficiency need to be modernized and automated, at an additional cost of $2 per specimen.

- Addition of other disorders to the screening: panel in the future (e.g., CF) would require additional fee increases.

- Inflationary increases in the cost of medical supplies and staffing, as well as further technological improvements, may require future fee increases.

Communicable Disease Testing

- The current categories of tests in ORS 431.310, created in 1967, are out of date, and the fee caps are no longer adequate to recover the costs of testing.

- Fees should be collected per test rather than per specimen, because several tests may now be performed on each specimen (e.g., hepatitis A, B and C).

LEGISLATION:

- HB 2268 amends ORS 431.310 to remove specific testing categories and sets a fee cap of $50 per test, while dedicating the revenue for use in the PHL.

- All fee increases would require a public rulemaking process and oversight and reporting as specified in ORS 291.055 and 291.060.

PROPOSED IMPLEMENTATION:

- October 1, 2001: begin screening Oregon newborns for congenital adrenal hyperplasia.
- January 1, 2002: begin MS/MS screening of all Oregon newborns, to detect the following disorders:

  Amino Acid Disorders Phenylketonuria (PKU), maple syrup urine disease (MSUD), tyrosinemia (types I and 11), homocystinuria.
  "Currently screened for by 1960's-era method, to be replaced by MS/MS.

  Urea Cycle Disorders Citrullinemia, argininosuccinate lyase deficiency (ASA).

  Organic Acidemias Isovale acyl-CoA dehydrogenase deficiency (Isovaleric acidemia), 3–methylcrotonyl-CoA carboxylase deficiency, 3-methylglataconyl-CoA hydratase deficiency, 3-hydroxy-3-methylglutaryl-CoA lyase dcficiency, propionic acidemia (PA), methylmalonic acidemia (MMA), 5-oxoprolinuria.

  Fatty Acid Oxidation Disorders Very long chain acyl-CoA dehydrogenase deficiency (VLCADD), long chain L-3 hydroxyacyl-CoA dehydrogenase deficiency (LCHADD), medium chain acyl-CoA dehydrogenase deficiency (MCADD), shQrt chain acyl-CoA debydrogenase deficiency (SCADD), glutaric aciduria, Type I (glutaryl-CoA dehydrogenase deficiency), glutaric aciduria, Type II (multiple acyl-CoA debydrogenase deficiency (MADD)), carnitine acylcarnitine translocase deficiency (CT), carnitine palmitoyl transferase II deficiency (CPT II).

- January 1, 2003: Automate galactosemia and biotinidese assays.